

ABSTRACT OF THE DISCLOSURE

The invention relates to a novel pharmaceutical sustained release formulation of guaifenesin. The formulation may comprise a hydrophilic polymer, preferably a hydroxypropyl methylcellulose, and a water-insoluble polymer, preferably an acrylic resin, in a ratio range of about one-to-one (1:1) to about six-to-one (6:1), more preferably a range of about three-to-two (3:2) to about four-to-one (4:1), and most preferably about two-to-one (2:1), by weight. This formulation capable of providing therapeutically effective bioavailability of guaifenesin for at least twelve hours after dosing in a human subject. The invention also relates to a modified release guaifenesin tablet which has two portion: the first portion comprises an immediate release formulation of guaifenesin and the second portion comprises a sustained release formulation of guaifenesin as described above. This two portion, or bi-layer, tablet has a maximum serum concentration equivalent to that of an immediate release guaifenesin tablet, and is capable of providing therapeutically effective bioavailability of guaifenesin for at least twelve hours after dosing in a human subject.